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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,430	01/12/2001	Lee R. Bolduc	105-C1	1423

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/759,430	Applicant(s) BOLDUC ET AL.	
	Examiner Darwin P. Erez	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-30 and 36-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16, 17, 19-30, 36, 38, 41-60 and 62-72 is/are rejected.
- 7) ☒ Claim(s) 15, 18, 37, 39, 40 and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 43, 44, 63, 65, 67, 69 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 recites withdrawing the anastomosis device from the first hollow tissue, which conflicts with the preamble of the claim since the claim is drawn to a method for anastomosing a first hollow tissue with a second hollow tissue using an anastomosis device. It is unclear how to maintain said "anastomosing" if the anastomosis device is withdrawn.

Claim 44 recites the limitation "the plurality of slot" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 63, 65, 67, 69 and 71 recite the limitation of "wherein the plurality of openings communicate with one another" which renders the claim vague and indefinite because it is unclear as to how the separate openings communicate with one another.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 14, 16, 17, 19-30, 36, 38, 41, 42, 45-60, 62, 64, 66, 68, 70 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,234,447 to Kaster et al.

Kaster teaches a method for an end-to-side anastomosis comprising the steps of providing an anastomosis device (**10,12**) having a plurality of openings (or slots defined in the core unit **14** having openings to secure the staple **12** within the sleeve **12**; also viewed as the means for holding the tissue securing elements); and a plurality of tissue securing elements having a first end a second end (**44,43**) and capable of being biased from an unbiased configuration to a biased configuration; holding the plurality of tissue securing elements in the biased configuration (Fig. 14); inserting the first end through the second hollow tissue (Fig. 17); permitting the plurality of the tissue securing element to move from the biased configuration to the unbiased configuration (transitioning from Fig. 17-19); wherein the first end of the tissue securing elements contact the inner surface of the second hollow tissue and the second end of the tissue securing element contact the outer surface of the second hollow tissue (end of transition shown in Fig. 19), wherein the first end of the tissue securing elements are permitted to assume the unbiased configuration prior to the second end (Fig. 17); wherein the anastomosis is formed between a first blood vessel and a second blood vessel (which could be the aorta since the aorta is blood vessel); wherein both the first and second hollow tissues are compressed; wherein the first hollow tissue is everted prior to insertion to about 90 degrees, more or less (Fig. 15 and depending on the base of the angle); wherein the distal end of the first hollow tissue is compressed against the outer surface of the second hollow tissue (Fig. 17); wherein the first end of the tissue securing elements is

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inserted from an exterior surface toward the interior surface (since the tissue is everted; Fig. 15); wherein the device further comprises a hub having a bore (the diameter of element **46**) that receives the first hollow tissue; wherein the device comprises a body (element **46** can also be viewed as a body/sleeve);

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 14, 30, 45, 50, 52 are 58 provisionally rejected the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of copending Application No. 10/858,640. For double patenting to exist between the rejected claims and the patented claims, it must be determined that the rejected claims are not patentably distinct from the patented claims. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and

the recited patented claims and, if so, whether those differences render the claims patentably distinct.

Each of independent claims 14, 30, 45, 50, 52, 58 recite a method comprising the steps of providing an anastomosis device having a plurality of openings, a plurality of tissue securing elements capable of being biased from an unbiased configuration to a biased configuration, holding the plurality of tissue securing elements in said biased configuration; inserting the device into the second hollow tissue structure, and permitting the plurality of tissue securing elements to move to the unbiased configuration, wherein each of the first tissue securing element contacts the *inner surface* of the second hollow tissue structure and each of the second end of the tissue securing element contacts the *outer surface* of the second hollow tissue structure.

It is clear that all the elements of said independent claims are to be found in claim 17 of the copending application. The difference between the claims of the instant application and claim 17 of the copending application lies in the fact that claim 17 of the copending application includes additional elements (hub) and is thus much more specific. Thus the invention of claim 17 in the copending application is in effect a "species" of the "generic" invention of the instant application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the claims of the instant application is anticipated by the recited claim of the copending application, it is not patentably distinct.

It is noted that the limitation of contacting the inner surface of the second hollow tissue structure is inherently implied in claim 17 of the copending application because it

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is necessary for the device to contact the inner surface of the second hollow tissue structure in order to attach the first hollow tissue to the second hollow tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

7. Claims 15, 18, 37, 39, 40 and 61 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments, see page 13 of the Remarks, filed 11/22/05, with respect to the rejection(s) of claim(s) under 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kaster et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER